UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF INDIANA SOUTH BEND DIVISION

GEORGE MAROUS,	
Plaintiff,	
v.	Cause No. 3:14-cv-768 RLM-MGG
BIOMET, INC., et al.,	
Defendants.	
YOLANDA CHISOLM,	
Plaintiff,	
v.	Cause No. 3:14-cv-1647 RLM-MGG
BIOMET, INC., et al.,	
Defendants.	
JOSEPH CECIL,	
Plaintiff,	
v.	Cause No. 3:14-cv-1712 RLM-MGG
BIOMET, INC., et al.,	
Defendants.	
JERRY AND SUSAN BAUMAN,	
Plaintiffs,	
v.	Cause No. 3:14-cv-1783 RLM-MGG
BIOMET, INC., et al.,	
Defendants.	
NINA GLASSER,	

Plaintiff,	
v.	Cause No. 3:14-cv-2057 RLM-MGG
BIOMET, INC., et al.,	
Defendants. ************************************))
WILLIAM C. WHITEN, as Personal Representative of the Estate of VIRGINIA BAKER, Deceased,)))
Plaintiff,	
v.) Cause No. 3:15-cv-147 RLM-MGG
BIOMET, INC., et al.,	
Defendants.))

OPINION AND ORDER

Each of these plaintiffs received Biomet M2a Magnum, M2a-38 or M2a Taper metal-on-metal hip implants, and sues Biomet for injuries stemming from alleged defects in the product. Biomet moves for summary judgment, arguing that because none of the plaintiffs preserved the explanted device, each should be sanctioned with dismissal. The court disagrees.

I. BACKGROUND

Early in the multi-district litigation related to the Biomet M2a hip implants, I ordered "[a]ll parties [] to take reasonable steps to preserve documents and other records (including electronic documents) containing

information potentially relevant to the subject matter of this litigation." Pretrial Order #1 ¶ 13, Oct. 12, 2012 [3:12-md-2391, Doc. No. 3].

On March 7, 2013, I issued an "Explant Preservation Order" requiring preservation of M2a devices removed from plaintiffs during revision surgeries, thus aiding in proving or disproving causation of injuries. The order imposes the following obligations:

- "A plaintiff shall make good faith efforts to ensure that non-party medical practitioners, hospitals, and vendors . . . preserve his or her Explanted M2a Devices" Explant Pres. Order § VI, Mar. 7, 2013 [3:12-md-2391, Doc. No. 279].
- "With respect to M2a Devices that have not yet been explanted or have been explanted but are not in either party's possession, counsel for a plaintiff may elect to obtain plaintiff's Explanted M2a Device from plaintiff's surgeon or the hospital where the surgery occurred and send it to a contract laboratory of plaintiff's choice or a designated storage facility. If plaintiff's counsel does not elect to obtain an Explanted M2a Device within 60 days of the revision surgery, Biomet will make arrangements for it to be sent to Malcolm Naylor of Biomet in Warsaw, Indiana." *Id.* § III(A).
- Each party must notify the other if that party has the explanted device in its possession prior to the date of the order. *Id.* § III(B).
- Each party must handle the explanted device in accordance with a Retrieval Analysis Protocol described in the order or a procedure that's

consistent with methods and practices accepted by those in the field of inspection and testing of orthopaedic devices. *Id.* § II.

• Each party in possession of the explanted device shall make the device available to the other party after inspection and testing. *Id.* § III(C).

Before the start of the MDL, the FDA used its powers under Section 522 of the Federal Food, Drug, and Cosmetic Act to require Biomet to conduct a postmarket surveillance study. Biomet had to submit a plan to conduct surveillance that would identify "the modes and causes of failure based on analysis of [Biomet's] reasonably available explanted retrieved devices."

A. George Marous, 3:14cv768

George Marous was implanted with a Biomet M2a-Magnum hip implant. He contacted a law firm in December 2012 about problems with the implant and spoke to a paralegal there, who referred him to his current counsel. In April 2013 Mr. Marous underwent revision surgery. Before the surgery he signed a form consenting to disposal "of any tissues, parts, or organs which may be removed." In an affidavit, he says that he requested the explant components before going into surgery. He and his wife say in affidavits that she spoke to the surgeon after surgery about retrieving the explant, but the surgeon said the request couldn't be fulfilled because bone was attached. At his deposition, Mr. Marous says he didn't know he could ask the hospital to preserve the explant. Joe Richardson, Jr., an independent contractor for "Biomet Mid Ohio," a Biomet distributor, was

present at the surgery. He says he was never instructed to retrieve the explanted device and didn't do anything to retrieve it.

Mr. Marous hired his current counsel in May 2013. They represent that they made an effort to contact the hospital's Department of Pathology after the revision to retrieve the explanted device, but the department said it never received the device. Mr. Marous filed suit in this court in April 2014.

B. Yolanda Chisolm, 3:14cv1647

Ms. Chisolm was implanted with a Biomet M2a-38 hip implant. In March 2014, her doctor told her that she needed revision surgery, tested high for cobalt and chromium, and suffered bone loss. Ms. Chisolm says that at this time she was aware of lawsuits involving Biomet and metal-on-metal hip implants. According to interrogatories, she first contemplated hiring an attorney in February 2014, and she first contacted an attorney at the end of March 2014.

She filed suit against Biomet in North Carolina state court in April 2014, before her revision surgery the following month. Before revision, she signed a form authorizing her "physician, other practitioners and the Hospital [to] examine any organs, tissues, other body parts or foreign bodies that are removed from [her] during the Surgery and [to] ke[ep], use[] and save[] [them] for scientific, educational or research purposes or dispose[] of [them] according to Hospital policies." Eric Owens, a Biomet sales representative, was present at the revision surgery. Ms. Chisolm says she doesn't know what happened to the device after it was removed from her.

After the revision surgery, Biomet removed the case to federal court, and it was then transferred to this court as part of this MDL docket.

C. Joseph Cecil, 3:14cv1712

Joseph Cecil was implanted with a Biomet M2a-Taper hip implant in 2005. In 2013 his doctor told him that he suffered from metallosis and needed revision surgery. Mr. Cecil says that at that time he wasn't aware of litigation and possible defects in metal-on-metal hip implants. Later that year, Mr. Cecil considered hiring an attorney. About two weeks before his revision surgery, he learned about problems with the DePuy and Stryker hip implants and went to a law firm. At that point, he says, he believed his injury was the result of his hip implant.

At the request of Mr. Cecil's wife, he signed a "Release of Specimens or Other Items" form, in which he requested that the "Left Hip Implant (Socket)" not be destroyed after surgery, but be released into his possession. Mr. Cecil underwent revision surgery in December 2013 and the hip implant was removed. After the revision surgery, Mr. Cecil never heard whether the hospital actually preserved that portion of the device, and neither he nor his wife ever received it. Mr. Cecil didn't follow up to see that the device was preserved or delivered to him, and he said he only learned that the explanted component hadn't been preserved on the day before his deposition.

He filed suit in federal court in Kentucky in April 2014 and the case was transferred to this court as part of this MDL docket.

D. Jerry Bauman, 3:14cv1783

Jerry Bauman was implanted with a Biomet M2a Magnum hip implant in 2008. After one and a half to two years with the device, Mr. Bauman began to experience pain and noticed a clicking sound in his hip. In late 2012, he met with a surgeon who recommended a revision surgery, explaining that the device wasn't positioned correctly and that he showed signs of a pseudotumor. Before undergoing the revision, Mr. Bauman signed a form that, among other things, authorized "disposal of any blood, fluid, specimen, or tissues which may be removed" during the surgery. The revision surgery took place in December 2012, and the device was removed. During his deposition, when asked what happened to the device after it was removed, Mr. Bauman said he didn't know.

In 2014 Mr. Bauman filed his complaint and joined this MDL docket.

E. Nina Glasser, 3:14cv2057

Nina Glasser was implanted with a Biomet M2a-Magnum hip implant in 2007. In January 2014, Ms. Glaser had her first revision surgery, during which the device's femoral head was replaced with a non-Biomet part. Ms. Glasser asked the doctor for the explanted part and the doctor gave it to her in a plastic bag provided by the hospital. Ms. Glasser left the plastic bag containing the part in a shopping bag in the bottom of her closet. In explaining why she asked for the explanted part, Ms. Glasser said: "I figured I paid for it. I wanted it."

Ms. Glasser underwent a second revision surgery in April 2014, during which the femoral head was replaced again with a Biomet part. After the second

revision, Ms. Glasser said she became aware of potential problems with metal-on-metal hip implants when she saw on television that certain implants had been recalled. She called her doctor about the recall and found out that the recall didn't apply to Biomet devices. She said she thought about contacting an attorney and contacted the firm that represents her now in May 2014.

Ms. Glasser underwent her final revision on July 2014, during which the acetabular cup was replaced. Before this revision, Ms. Glasser signed a form providing her consent to "disposal [of the explanted parts] according to the hospital policies and the recommendations of the physician." Biomet doesn't present evidence that she had retained an attorney by this time.

Ms. Glasser filed suit in November 2014 in federal court in Kentucky and the case was then transferred to this court as part of this MDL docket. On the "Plaintiff Fact Sheet" Ms. Glasser returned to Biomet in May 2015, she filled out "NA" when asked "what is the present location of the removed components of the M2a Device?" She never filed an amended fact sheet to explain that she had the femoral head in her possession. Biomet says that Ms. Glasser only disclosed to Biomet that she had a third revision surgery on the date of her deposition.

F. Virginia Baker, 3:15cv147

Virginia Baker¹ was implanted with a Biomet M2a-Magnum hip implant in 2008. In 2012 she learned she suffered from metallosis when her doctor told her she had elevated cobalt and chromium levels. After seeing an advertisement for

¹ Ms. Baker has since passed away. William Whiten is continuing the suit on behalf of her estate.

attorneys, she called and retained counsel in February 2014. In December 2014, Ms. Baker underwent revision surgery in which the Magnum components were removed.

Before the surgery, Ms. Baker filled out a form authorizing the "physician or the pathologist to examine, retain for scientific and/or educational purposes, or dispose of all such tissues, organs, or bodily fluids that shall be removed by operation." She didn't ask the hospital to preserve the explanted device or ask to be able to take it home from the surgery. She said she was unaware of what happened to the device after surgery. Bradford Anglin, an employee of Jazz Medical, a Biomet distributor, attended the revision surgery. He didn't do anything to preserve the device either, and said that he couldn't because it was against policy.

Ms. Baker filed suit against Biomet in the MDL docket in this court in April 2015.

II. STANDARD OF REVIEW

Biomet moves for summary judgment on grounds that each plaintiff's failure to preserve the explanted M2a components was negligent and violated the preservation orders. Biomet asks the court to sanction each plaintiff with dismissal of her case and costs. Some of the plaintiffs ask that the court sanction Biomet for not preserving the device and award attorney's fees for bringing a frivolous motion.

Summary judgment is appropriate when the pleadings, discovery materials, disclosures, and affidavits demonstrate no genuine issue of material fact, and the movant is entitled to judgment as a matter of law. Protective Life Ins. Co. v. Hansen, 632 F.3d 388, 391-92 (7th Cir. 2011). I must construe the evidence and all inferences that reasonably can be drawn from the evidence in the light most favorable to the non-moving party. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1986). As the moving party, Biomet must inform me of the basis for its motion, together with evidence demonstrating the absence of any genuine issue of material fact. Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). If Biomet meets that burden, a plaintiff can't rest upon the allegations in the pleadings, but must "point to evidence that can be put in admissible form at trial, and that, if believed by the fact-finder, could support judgment in his favor." Marr v. Bank of America, N,A., 662 F.3d 963, 966 (7th Cir. 2011); see also Hastings Mut. Ins. Co. v. LaFollette, No. 1:07-cv-1085, 2009 WL 348769, at *2 (S.D. Ind. Feb. 6, 2009) ("It is not the duty of the court to scour the record in search of evidence to defeat a motion for summary judgment; rather, the nonmoving party bears the responsibility of identifying the evidence upon which he relies."); Hammel v. Eau Galle Cheese Factory, 407 F.3d 852, 859 (7th Cir. 2005) (summary judgment is "not a dress rehearsal or practice run; it is the put up or shut up moment in a lawsuit, when a party must show what evidence it has that would convince a trier of fact to accept its version of events").

III. DISCUSSION

A. Rule 37

Biomet argues that each of these plaintiffs violated the preservation orders when he or she didn't preserve the explanted M2a device, and so she should be sanctioned with dismissal and attorneys' fees. A court may impose sanctions, including dismissal of the action, on a party who disobeys a discovery order. Fed. R. Civ. P. 37(b)(2)(A)(v). A court also "has inherent power to sanction a party who has willfully abused the judicial process or otherwise conducted litigation in bad faith." Secrease v. W. & S. Life Ins. Co., 800 F.3d 397, 401 (7th Cir. 2015).

Dismissal with prejudice "is a harsh sanction which should usually be employed only in extreme situations, where there is a clear record of delay or contumacious conduct,² or when other less drastic sanctions have proven unavailable." Marrocco v. Gen. Motors Corp., 966 F.2d 220, 224 (7th Cir. 1992). To dismiss a case in response to discovery order violations under Rule 37, the court must find "willfulness, bad faith or fault." Maynard v. Nygren, 332 F.3d 462, 467 (7th Cir. 2003). "Fault" doesn't have to do with subjective intent; rather, it "only describe[s] the reasonableness of the conduct—or lack thereof—which eventually culminated in the violation." Langley v. Union Elec. Co., 107 F.3d 510, 514 (7th Cir. 1997).

At a minimum, for a plaintiff to have violated a discovery order that would subject her to Rule 37 sanctions, he or she must have been bound by the

² "A willful disobedience of a court order." <u>Contumacious Conduct</u>, Black's Law Dictionary (7th ed. 1999).

discovery order when it was possible for her to comply. None of these plaintiffs were.

Biomet cites no cases that support the proposition that a plaintiff is subject to the orders of an MDL court *before* that plaintiff has joined the MDL. Biomet cites Bennett v. Bayer Healthcare Pharmaceuticals, Inc., 577 F. App'x 616 (7th Cir. 2014) for this proposition, but Bennett offers no such support. The plaintiff in that case was bound by an MDL court's discovery order that predated her transfer to the MDL court, but the court order only bound her once her case was transferred to the MDL court and she was still able to comply. In contrast:

None of these plaintiffs' cases had been transferred to this court by the time of the revision surgery. Ms. Baker, Mr. Marous and Mr. Bauman hadn't filed any case at all by the time of the revision surgery. With respect to all plaintiffs except Ms. Glasser, compliance with any obligation to preserve the explant appears to have been impossible by the time he or she joined the MDL. For Ms. Glasser, compliance appears to have been impossible for the device removed during her final revision surgery.

Biomet cites <u>Langley v. Union Electric Co.</u>, 107 F.3d 510 (7th Cir. 1997) for the proposition that spoliation before a discovery order is still sanctionable under Rule 37. The <u>Langley plaintiff</u> was sanctioned only after being uncandid with the court about losing evidence, and then disobeying a court order to produce it. <u>Langley v. Union Elec.</u>, 107 F.3d at 514 ("Having reentered his order and waited in vain for the furnace, the judge imposed sanctions in March 1995. Because appellant was in violation of the order to produce the furnace, the

sanctioning was a perfectly legitimate exercise of power under Rule 37(b)."). The plaintiff also shirked arrangements with the defendant to provide the evidence. *Id.* At any rate, the court order in <u>Langley</u> took place only after the plaintiff's case was in the relevant court.

None of the relevant facts applies to any of these plaintiffs. None of these plaintiffs willfully disobeyed a court order because none was bound by a court order until following its directives was impossible. None of these plaintiffs promised to deliver the explant to Biomet, and none hid that such evidence was missing.

Rule 37 is no help to Biomet because none of these plaintiffs violated a discovery order. The court's discovery orders can only direct behavior of parties who are able to comply. As to a non-party, the court is merely shouting into a void, and there's no logic in penalizing the person who doesn't happen to hear it. As to the one who's unable to comply with a discovery order that pre-dated transfer and has only been forthright about it, sanctions are neither just nor productive. *See also* 8B Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure, § 2283 (3d ed. 2016) ("[B]efore imposing a serious merits sanction the court should determine whether the party guilty of a failure to provide discovery was unable to comply with the discovery.").3

³ Both the Explant Preservation Order and its amended version, Am. Explant Pres. Order, Nov. 24, 2015 [3:12-md-2391, Doc. No. 3008], define "M2a Device" as "the following Biomet M2a Hip System Device and components marketed and sold by defendants to plaintiffs in the United States: M2a Magnum and M2a 38." Notably, neither document includes the Biomet M2a-Taper within the definition of "M2a Device." The document, by its own terms, thus doesn't cover the device explanted from Mr. Cecil, even though the M2a-Taper was added to the MDL about a month after the original Explant Preservation Order and about two and a half years before the amended version.

Ms. Glasser's obligations once she took the explanted femoral head from her first revision surgery home are different. At the time of the revision, for the reasons already explained, Ms. Glasser wasn't bound by the court's preservation orders. But once the case was transferred to this MDL docket, under Bennett, she was obligated to follow the orders to the extent possible and, under at least two provisions, she didn't meet the order's requirements.

Under the Explant Preservation Order, "[a] party that has an Explanted M2a Device in its possession shall provide notice to the other party..." Explant Pres. Order § III(B)(1), Mar. 7, 2013 [3:12-md-2391, Doc. No. 279]. Ms. Glasser violated this provision by not disclosing her possession of the femoral head to Biomet once she joined the MDL.

The order also requires each party to handle the explanted device in accordance with a Retrieval Analysis Protocol described in the order or a procedure that's consistent with methods and practices accepted by those in the field of inspection and testing of orthopaedic devices. *Id.* § II. Similarly, once Ms. Glasser had joined the MDL and was bound by the order, it was her job to make sure the device was preserved appropriately, not simply left in her closet.

Whether Ms. Glasser's violations are enough to merit dismissal is a different story. Dismissal with prejudice "is a harsh sanction which should usually be employed only in extreme situations, where there is a clear record of delay or contumacious conduct, or when other less drastic sanctions have proven unavailable." Marrocco v. Gen. Motors Corp., 966 F.2d 220, 224 (7th Cir. 1992). There's no "clear record of delay" here. There's no evidence that Biomet

ever tried to retrieve the device from Ms. Glasser or from the hospital until it brought this motion, and Ms. Glasser was then perfectly forthcoming. There's no evidence of "contumacious conduct" because she obtained the component before she was bound by the order and nothing suggests that her non-disclosure was more than an oversight. Her filling in "NA" on the Plaintiff Fact Sheet when asked about the present location of the retrieved components also doesn't show, without genuine dispute, that she acted willfully. There haven't been any lesser attempts to sanction her. Dismissal isn't warranted on these grounds.

B. Fault.

Fault is another avenue for the court to issue sanctions, even if not for violation of a binding discovery order under Rule 37(b), then under the court's inherent powers. Marrocco v. Gen. Motors Corp., 966 F.2d 220, 224 (7th Cir. 1992). "Fault" refers to "the reasonableness of the conduct – or lack thereof – which eventually culminated in the violation." *Id.* "A dismissal with prejudice is a harsh sanction which should usually be employed only in extreme situations" Barnhill v. United States, 11 F.3d 1360, 1367 (7th Cir. 1993).

Nothing suggests that any of these plaintiffs acted at all unreasonably, let alone to an extent justifying dismissal. Biomet provides no reason why a patient would think that preserving the device is a real option to her, let alone that she should do it to comply with a court order about which she knows nothing. Biomet doesn't show that signing a paper authorizing the hospital to dispose of the device would be unreasonable in the circumstances. Biomet provides no evidence

that an attorney advised any of the plaintiffs to preserve the device before revision. Biomet provides no law imputing an attorney's knowledge of a duty to preserve the device to her client.

Mr. Marous's affidavit about requesting the device before his surgery might contradict his deposition statement about not seeking preservation, but that possibility doesn't provide the proof Biomet needs. If Mr. Marous tried to take the device home and his surgeon refused, I'm not sure why a reasonable patient would do anything more.

If Mr. Cecil's wife was proactive in seeking preservation, she took a step that seems extraordinary for the lay patient. Whether the hospital would simply provide a 'to-go' container for the device at the end of the surgery or send it sometime in the future might not have been clear. Once Mr. Cecil filed his suit, nothing would have stopped Biomet from requesting the device from Mr. Cecil or the hospital.

Ms. Glasser's request for the femoral head seems to be unusual only in that I don't expect a reasonable patient to request the device or its preservation at all, and if she hadn't it would have been lost irretrievably. Ms. Glasser can't be blamed for not knowing proper methods for storing her femoral head, and she seems to have requested it more as a novelty item than out of a desire to preserve evidence for litigation. Biomet doesn't show that then signing a paper authorizing the hospital to dispose of the acetabular cap was unreasonable.

C. Spoliation

Biomet discusses <u>Trask-Morton v. Motel 6 Operating L.P.</u>, 534 F.3d 672, 681 (7th Cir. 2008) for the proposition that a spoliation sanction is proper where "a party has a duty to preserve evidence because it knew, or should have known, that litigation was imminent."

When a plaintiff, such as Ms. Glasser or Ms. Chisolm, contacted or retained an attorney before revision surgery, I might be able to infer that she knew litigation to be imminent at the time of surgery. Reasonable knowledge of imminent litigation is a necessary, not a sufficient condition for spoliation sanctions. *Id.* ("[C]ourts have found a spoliation sanction to be proper *only where* a party has a duty to preserve evidence because it knew, or should have known, that litigation was imminent.") (emphasis added). Another "prerequisite" for this route to spoliation sanctions is "bad faith," "destruction for the purpose of hiding adverse information." *Id.* Biomet doesn't provide evidence that any of the plaintiffs intended to hide adverse information.

Under either Rule 37 or the court's inherent powers, Biomet doesn't demonstrate that, as a matter of law, a judgment of dismissal is warranted with respect to any of these plaintiffs.⁴

 $^{^4}$ The court provides no answer as to whether sanctions are available under state law and leaves any such question to the court that receives this case on remand. See Sch. Order ¶ 4(E), Dec. 21, 2015 [3:12-md-2391, Doc. No. 3047] ("Biomet represents that its argument . . . will be that a plaintiff failed to comply with this court's preservation order included in the October 12, 2012 order. Issues of failure to comply with a federal court's order should pose no state law issues, and alleged violations of a federal court order are to be resolved by the issuing court. If a summary judgment motion under this paragraph should exceed these parameters, counsel should call it to my attention.").

D. Sanctions Against Biomet

The plaintiffs also argue that the loss of the device was Biomet's fault and that Biomet should be sanctioned with dismissal under the same principles. They argue that the Explant Preservation Order directs Biomet to make arrangements within 60 days of revision surgery for explanted devices to be sent to Biomet's facility in Warsaw, Indiana. This is true, but Biomet also isn't bound to comply with a discovery order from the MDL court addressing a plaintiff who's not yet part of the MDL.

Second, these plaintiffs argue that a Biomet representative was present during their surgeries and could have made sure the explant was preserved. There isn't enough evidence to decide this fact as beyond dispute. For some, it wasn't clear that a representative was present. Even when there's no dispute that a representative attended, it's not clear she had authority to take the device or to have it preserved.

Third, each of the plaintiffs argues that the FDA required Biomet to preserve explanted components as part of its required postmarket surveillance. The FDA's letter, however, only indicates that preservation is required for devices included in the "cross-sectional study" Biomet conducts as part of its postmarket surveillance plan. None of these plaintiffs provides evidence that he or she was part of that study.

Biomet might have been able to act affirmatively to facilitate preservation of devices, for example by sending letters to doctors and customers to make sure

that devices are so preserved. That Biomet didn't do so, however, doesn't mean that it had a court-ordered duty to preserve the explants of people who weren't yet parties to the MDL, or that Biomet was negligent for losing the device.⁵

IV. CONCLUSION

The court thus DENIES Biomet's motions for summary judgment [3:14cv-768, Doc. No. 131] [3:14-cv-1647, Doc. No. 140] [3:14-cv-1712, Doc. No. 133] [3:14-cv-1783, Doc. No. 136] [3:14-cv-2057, Doc. No. 127] [3:15-cv-147, Doc. No. 119].

SO ORDERED.

ENTERED: March 1, 2017

/s/ Robert L. Miller, Jr. Judge United States District Court

⁵ Ms. Chisolm and Mr. Bauman also ask that I award them attorney's fees for the cost of responding to Biomet's "baseless" motion. Those requests amount to motions that had to be filed separately so that Biomet had ample opportunity to respond. N.D. Ind. L.R. 7-1(a).